Initial Statement of Reasons for

Proposed Amendments to California Code of Regulations,

Title 18, Section 1591, *Medicines and Medical Devices*

SPECIFIC PURPOSE, PROBLEMS INTENDED TO BE ADDRESSED, NECESSITY, AND ANTICIPATED BENEFIT

Current Law

California imposes sales tax on retailers for the privilege of selling tangible personal property at retail. (Rev. & Tax. Code, § 6051.) Unless an exemption or exclusion applies, the tax is measured by a retailer's gross receipts from the retail sale of tangible personal property in California. (Rev. & Tax. Code, §§ 6012, 6051.) The term "gross receipts" means the total amount of the sale price without any deduction for the cost of materials used, labor or service costs, interest paid, losses, or any other expense. (Rev. & Tax. Code, § 6012, subd. (a)(2).) Although sales tax is imposed on retailers, retailers may collect sales tax reimbursement from their customers if their contracts of sale so provide. (Civ. Code, § 1656.1; Cal. Code Regs., tit. 18, § 1700, subd. (a)(1).)

When sales tax does not apply, use tax is imposed, measured by the sales price of property purchased from a retailer for storage, use, or other consumption in California. (Rev. & Tax. Code, 6201, 6401.) The use tax is imposed on the person actually storing, using, or otherwise consuming the property. (Rev. & Tax. Code, § 6202.) However, every retailer "engaged in business" in California that makes sales subject to California use tax is required to collect the use tax from its customers and remit it to the State Board of Equalization (Board), and such retailers are liable for California use tax that they fail to collect from their customers and remit to the Board. (Rev. & Tax. Code, § 6203; Cal. Code Regs., tit. 18, § 1684.)

Revenue and Taxation Code (RTC) section 6369 provides an exemption from sales and use tax that applies to the sale or use of medicines that are dispensed, furnished, or sold under any of the circumstances prescribed by section 6369, subdivision (a)(1) through (6) (hereafter "statutorily prescribed circumstances"). As relevant here, section 6369, subdivision (b), defines "medicines" as "any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease and commonly recognized as a substance or preparation intended for that use." Section 6369, subdivision (b), further provides that certain items are excluded from the definition of medicines, including "(2) [a]rticles that are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices, or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof." Subdivision (c) of section 6369 describes additional specific items that are medicines, notwithstanding subdivision (b), and subdivision (c)(2) of section 6369 expressly provides that the term "medicines" means and includes "[b]one screws, bone pins, pacemakers, and other articles, other than dentures, permanently implanted in the human body to assist the functioning of any natural organ, artery, vein, or limb and which remain or dissolve in the body."

The Board adopted California Code of Regulations, title 18, section (Regulation) 1591, *Medicines and Medical Devices*, to implement, interpret, and make specific the exemption provided by RTC section 6369 and the structure of Regulation 1591 closely resembles the structure of RTC section 6369. As relevant here, Regulation 1591, subdivision (a)(9), currently defines "medicines" as follows:

> "Medicines" means:
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> > (A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition regardless of ultimate use, or
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> > (B) Any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use.
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> The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.

Subdivision (c) of Regulation 1591 provides that certain items are excluded from the definition of medicines, including "(2) [a]rticles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices, or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof . . . ." Notwithstanding subdivision (c), subdivision (b) of Regulation 1591 includes several categories of articles, devices and appliances (generally corresponding with those listed in RTC section 6369, subd. (c)), which are included in the definition of medicines, either generally or for specific uses, and, in some cases, subdivision (b) also identifies specific items that are included in or excluded from those categories. Currently, Regulation 1591, subdivision (b)(2), provides that "medicines" means and includes:

> (2) Permanently Implanted Articles. Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Except for devices excluded from the definition of "medicines," permanently implanted articles include the interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted. Tax does not apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

> Permanently implanted articles include, but are not limited to, permanently implanted artificial sphincters; bone screws and bone pins; dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants, including the ear implant's interdependent internal and external components. Sutures are also included whether or not they are permanently implanted. A non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture.
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> Implantable articles that do not qualify as "permanently" implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheters; temporary myocardial pacing leads used during surgery and recovery; and defibrillator programmer and high voltage stimulator used with an implanted defibrillator. The sale or use of these items is subject to tax.

Also, as relevant here, the Board's Legal Department has previously determined, as early as 1965, that diagnostic "opaques and dyes" are medicines as defined in RTC section 6369. This determination is found in Sales and Use Tax Annotation[1] 425.0580, which provides as follows:

> **Opaques and Dyes.** Opaques and dyes used by hospitals and doctors in examination of patients are given internally to the patients and facilitate the taking of diagnostic x-ray photographs. Since such opaques and dyes are intended for use by internal application to the human body in diagnosis of disease they qualify as medicines under section 6369 of the Revenue and Taxation Code. 9/1/65.

Furthermore, as relevant here, the United States Food and Drug Administration's (FDA's) website explains that:

- "The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act (the act) established three regulatory classes for medical devices. The three classes are based on the degree of control necessary to assure that the various types of devices are safe and effective. The most regulated devices are in Class III. The amendments define a Class III device as one that supports or sustains human life or is of substantial importance in preventing impairment of human health or presents a potential, unreasonable risk of illness or injury. Insufficient information exists on a Class III device so that performance standards (Class II) or general controls (Class I) cannot provide reasonable assurance that the device is safe and effective for its intended use. Under Section 515 of the act, all devices placed into Class III are subject to premarket approval requirements. Premarket

[1] Annotations, which are published in the Business Taxes Law Guide**,** are summaries of conclusions reached in selected legal rulings by staff counsel, as applied to specific factual situations. Annotations do not embellish or interpret the legal rulings of counsel which they summarize and do not have the force and effect of law. (See, Cal. Code Regs., tit. 18, § 5700, *Annotations*.)

approval by FDA is the required process of scientific review to ensure the safety and effectiveness of Class III devices."[2]

- "Each person who wants to market in the U.S., a Class I, II, and III device intended for human use, for which a Premarket Approval (PMA) is not required, must submit a 510(k) to FDA unless the device is exempt from 510(k) requirements of the Federal Food, Drug, and Cosmetic Act (the Act) and does not exceed the limitations of exemptions in .9 of the device classification regulation chapters (e.g., 21 CFR 862.9, 21 CFR 864.9). . . . Before marketing a device, each submitter must receive an order, in the form of a letter, from FDA which finds the device to be substantially equivalent (SE) and states that the device can be marketed in the U.S. This order 'clears' the device for commercial distribution."[3]

Proposed Amendments

Breast Tissue Markers (BTMs) are sterile disposable medical devices that are comprised of an introducer needle and applier as well as a radiographic (i.e., readable by x-ray or other imaging technologies), implantable titanium or metal alloy marker. BTMs are placed in soft breast tissue during surgical or percutaneous (i.e., performed through the skin) biopsies for the purpose of marking the site where the tissue sample was taken so that it can be accurately identified by ultrasound, magnetic resonance imaging (MRI), or other imaging methods at a future date.

During the Board's February 2014 meeting, the Board heard a sales and use tax appeal concerning whether breast tissue markers (BTMs) are medicines and therefore exempt from tax under RTC section 6369 when sold or furnished under the statutorily prescribed circumstances. During the hearing, it was established that BTMs are fully implanted. BTMs are used to diagnosis breast cancer, and perform an almost identical function to diagnostic opaques and dyes that are injected into the body for the purpose of appearing on imaging technologies. And, the BTMs at issue were Class II medical devices that the FDA cleared under the 510(k) process discussed above, but the BTMs were not subject to the FDA's premarket approval process and did not receive the FDA's premarket approval. Therefore, the Board determined that the BTMs at issue are "medicines" for purposes of the exemption provided by RTC section 6369. The Board also recognized that there were issues (or problems within the meaning of Gov. Code, § 11346.2, subd. (b)) because Regulation 1591 does not specifically address medical devices that are permanently implanted to mark the location of a medical condition, and does not clearly explain what type of FDA approval is required in order for a medical device to qualify as a medicine. Therefore, to address the issues, the Board directed Board staff to initiate a rulemaking process to clarify the application of Regulation 1591 to Class II medical devices that are fully implanted.

Interested Parties Process

[2] The quoted information is available at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm.

[3] The quoted information is available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm.

Originally, the Board's Business Taxes Committee (BTC) staff prepared draft amendments to subdivisions (a)(9) and (b)(2) of Regulation 1591 to address the issues described above. The draft amendments suggested moving and slightly amending the reference to subdivision (c) in subdivision (a)(9)(A). The draft amendment to subdivision (a)(9) also included language clarifying that products "approved" by the FDA include products for which an application for pre-market notification was cleared and products that received the FDA's premarket approval. The draft amendment to subdivision (b)(2) clarified that articles permanently implanted in the human body to mark the location of a medical condition, such as breast tissue markers, qualify as medicines. The draft amendments also included non-substantive changes to the regulation to correct grammatical and formatting errors.

BTC staff subsequently provided its draft amendments to the interested parties and conducted an interested parties meeting on June 16, 2014. During the June 2014 meeting, the interested parties supported the proposed amendments to Regulation 1591 regarding FDA approval and BTMs. They did not agree, however, that staff's other proposed amendment would actually clarify subdivision (a)(9)(A) of the regulation. Moreover, Mr. Wade Downey of Downey, Smith & Fier disagreed with staff's analysis with regard to the application of subdivision (a)(9)(A) and contended that it is not clear to taxpayers, from the current text of subdivision (a)(9)(A), that they must also look to subdivisions (b) and (c) to determine if a product qualifies as a medicine.

On June 26, 2014, staff received letters from Mr. Downey and from Mr. Jacob Bholat of Equity Recovery Solutions, Inc. Mr. Downey's letter stated that staff's proposed changes did not resolve the confusing structure of Regulation 1591 and suggested that any product that is "approved" by the FDA and fully implanted or injected in a patient for a medical purpose should be exempt based on subdivision (a)(9)(A) of the regulation, alone. Mr. Bholat's letter suggested removing language that specifically excludes certain products (other than BTMs) from the definition of medicine in (b)(2).

In response to the interested parties' comments, staff decided not to pursue the proposed amendment moving and slightly amending the reference to subdivision (c) in subdivision (a)(9)(A) of Regulation 1591 because of the interested parties' belief that it did not clarify the regulation. Staff also decided to keep the reference to subdivision (c) in subdivision (a)(9)(A) because the removal of the reference to subdivision (c) would substantially change the meaning of subdivision (a)(9)(A) in a manner that would be inconsistent with RTC section 6369, and because there is no basis to delete the provisions of subdivision (c), which list items, including devices, that are specifically excluded from the definition of medicines.

On August 14, 2014, staff again met with the interested parties to discuss the draft amendments. The interested parties continued to disagree with staff regarding the application of subdivision (a)(9)(A) of Regulation 1591. The interested parties believed that the exclusion from the definition of medicine contained in subdivision (c)(2) of Regulation1591 did not include all devices. Mr. Bholat also pointed out that the last sentence in subdivision (b)(2) of the regulation, stating that the sale of products specifically excluded from the definition of medicines under that subdivision are subject to tax, does not account for the possibility that such products could meet a different definition of medicine.

On August 28, 2014, staff received an email from Mr. Downey requesting that staff's original proposed amendment to subdivision (a)(9)(A) of Regulation 1591 be reinstated because it read better and that language should be added to the regulation to except fully implanted articles from the exclusion from the definition of medicine in subdivision (c)(2) of Regulation 1591. Mr. Downey included an attachment with his proposed changes. On September 3, 2014, staff received an email from Mr. Bholat, which also recommended revised language for subdivision (a)(9)(A) and an exception for fully and permanently implanted articles from the exclusion contained in subdivision (c)(2). Mr. Bholat also recommended adding a sentence to the end of the third paragraph in subdivision (b)(2) of Regulation 1591 stating that the "sale or use of [the] types of items [specifically excluded from the definition of medicine by that paragraph], would be subject to tax, if intended for temporary placement." Mr. Bholat also included an attachment with his proposed changes.

November 19, 2014, BTC Meeting

In response to the interested parties' concerns about clarity, BTC staff recommended inserting a final sentence at the end of subdivision (a)(9) of Regulation 1591 reiterating that the term "medicines" is further defined in subdivisions (b) and (c). Staff did not agree with either of the interested parties' suggested amendments to subdivision (a)(9)(A) because, as before, staff did not believe the amendments clarified the existing language and because Mr. Bholat's language would have actually narrowed the definition by removing the phrase "for all uses," which is currently in subdivision (a)(9)(A). Staff also agreed with Mr. Bholat's comment from the August 14, 2014, meeting that the items specifically excluded from the definition of medicine under subdivision (b)(2) of Regulation 1591 could meet a different definition of medicine. However, staff believed that Mr. Bholat's recommended amendment to subdivision (b)(2) (discussed above) would create contradictions within the subdivision, expand the definition of medicine, make the regulation more ambiguous by adding an intent element, and create unnecessary complexity. Accordingly, staff recommended simply removing the final sentence of subdivision (b)(2). In addition, staff did not agree with either of the interested parties' proposed changes to subdivision (c)(2) of Regulation 1591 because the changes would have expanded the definition of medicine in Regulation 1591 so that it conflicts with the plain language of RTC section 6369.

Subsequently, BTC staff prepared Formal Issue Paper 14-006 and distributed it to the Board Members for consideration at the Board's November 19, 2014, BTC meeting. Formal Issue Paper 14-006 recommended that the Board: (1) add the language regarding FDA approval and BTMs to Regulation 1591, subdivisions (a)(9) and (b)(2), respectively; (2) add the reference to subdivisions (b) and (c) to the end of Regulation 1591, subdivision (a)(9); (3) remove the final sentence from Regulation 1591, subdivision (b)(2); (4) make non-substantive amendments to make the regulation grammatically correct and internally consistent; and (5) make no changes to Regulation 1591, subdivision (c)(2).

The Board discussed Formal Issue Paper 14-006 during its November 19, 2014, BTC meeting. Mr. Downey and Mr. Bholat appeared in support of their respective proposals. However, during the November 19, 2014, BTC meeting, Mr. Downey clarified that the interested parties were not necessarily opposed to staff's recommended amendments to Regulation 1591; the interested

parties primarily wanted more specific clarification regarding the relationships between subdivisions (b) and (c) of the regulation; and that they would be satisfied if the Board provided the necessary clarification in its Audit Manual. At the conclusion of the discussion, the Board Members unanimously voted to propose the amendments to Regulation 1591 recommended by staff and did not approve any changes to subdivision (c)(2) of the regulation. The Board also directed staff to draft guidance for inclusion in the Audit Manual that speaks to the interaction between subdivisions (a), (b), and (c) of the regulation, and share it with the interested parties.

The Board determined that the proposed amendments to Regulation 1591 are reasonably necessary for the specific purpose of addressing the issues (or problems) with Regulation 1591, discussed above, by clarifying the application of tax to medical devices that are permanently implanted to mark the location of a medical condition, and clearly explaining the types of FDA approval that are required in order for a medical device to qualify as a medicine.

The Board anticipates that the proposed amendments to Regulation 1591 will promote fairness and benefit taxpayers, Board staff, and the Board by providing clarity with regard to the application of the exemption provided by RTC section 6369 to medical devices that are permanently implanted to mark the location of a medical condition, the type of FDA approval required by the regulation, and the interrelation between subdivisions (a) through (c) of the regulation.

In addition, the Board has determined that the proposed amendments are not mandated by federal law or regulations, and there are no federal regulations or statutes that are identical to Regulation 1591 or the proposed amendments to Regulation 1591.

DOCUMENTS RELIED UPON

The Board relied upon Formal Issue Paper 14-006, the exhibits to the issue paper, and the comments made during the Board's discussion of the issue paper during its November 19, 2014, BTC meeting in deciding to propose the amendments to Regulation 1591 described above.

ALTERNATIVES CONSIDERED

The Board considered whether to begin the formal rulemaking process to adopt the amendments to Regulation 1591 recommended by staff or the interested parties (discussed above), or some combination thereof, or, alternatively, whether to take no action at this time. The Board decided to begin the formal rulemaking process to propose to adopt staff's recommended amendments to Regulation 1591 at this time because the Board determined that the proposed amendments are reasonably necessary for the reasons set forth above.

The Board did not reject any reasonable alternative to the proposed amendments to Regulation 1591 that would lessen any adverse impact the proposed action may have on small business or that would be less burdensome and equally effective in achieving the purposes of the proposed action. No reasonable alternative has been identified and brought to the Board's attention that would lessen any adverse impact the proposed action may have on small business, be more effective in carrying out the purposes for which the action is proposed, would be as effective and

less burdensome to affected private persons than the proposed action, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law than the proposed action.

INFORMATION REQUIRED BY GOVERNMENT CODE SECTION 11346.2, SUBDIVISION (b)(5) AND ECONOMIC IMPACT ASSESSMENT REQUIRED BY GOVERNMENT CODE SECTION 11346.3, SUBDIVISION (b)

As previously explained, the proposed amendments clarify the current provisions of Regulation 1591, subdivision (a)(9), by explaining that products approved by the FDA means any product for which the FDA cleared a premarket notification or approved an application for premarket approval, to make the regulation consistent with the FDA's "approval processes" (discussed above) and the Board's February 2014 decision (discussed above). The proposed amendments clarify the current provisions of Regulation 1591, subdivision (a)(9), by explaining that medicines are further defined in subdivisions (b) and (c) of the regulation. The proposed amendments clarify that articles permanently implanted in the human body to mark the location of a medical condition are included in the definition of medicines under Regulation 1591, subdivision (b)(2), to be consistent with the Board's historical treatment of opaques and dyes and the Board's February 2014 decision. The proposed amendments also make Regulation 1591, subdivision (b)(2), consistent with current law, by clarifying that the specific articles that do not qualify as medicines under the third paragraph in Regulation 1591, subdivision (b)(2), may meet the definition of medicines under a different subdivision. In addition, the proposed amendments make non-substantive changes to make the regulation grammatically correct and internally consistent.

The proposed amendments do not change the requirements for FDA approval in Regulation 1591, subdivision (a)(9), because the Board determined in its February 2014 decision that the provisions requiring "approval" by the FDA were not intended to be narrowly interpreted to mean pre-market approval. The proposed amendments to Regulation 1591, subdivision (a)(9), stating that medicines are further defined in subdivisions (b) and (c) do not change the application of any of the regulation's provisions because, currently, subdivisions (b) and (c) do further define the term medicines.

The proposed amendments to Regulation 1591, subdivision (b)(2), clarifying that articles permanently implanted in the human body to mark the location of a medical condition, such as BTMs, qualify as medicines do not change the meaning of the term medicines as used in RTC section 6369 and Regulation 1591 because the Board has historically treated opaques and dyes as medicines, the devices being added to subdivision (b)(2) perform the same function as opaques and dyes, and the Board previously determined that BTMs are medicines in its February 2014 decision. The proposed amendments deleting the last sentence from the third paragraph in Regulation 1591, subdivision (b)(2), do not change current law, which does permit specific articles that do not qualify as medicines under the third paragraph in Regulation 1591, subdivision (b)(2), to qualify as medicines under other provisions in Regulation 1591, and deleting the sentence removes any potential ambiguity.

Also, as previously explained, the Board anticipates that the proposed amendments to Regulation 1591 will promote fairness and benefit taxpayers, Board staff, and the Board by providing clarity

with regard to the application of the exemption provided by RTC section 6369 to medical devices that are permanently implanted to mark the location of a medical condition, the type of FDA approval required by the regulation, and the interrelation between subdivisions (a) through (c) of the regulation's provisions.

As a result, there is nothing in the proposed amendments to Regulation 1591 that would significantly change how retailers and consumers of medical devices would generally behave in the absence of the proposed amendments. In addition, the amendments to Regulation 1591 do not require that individuals and businesses do anything that is not currently required by RTC section 6369 or Regulation 1591, and do not impose any costs on any persons. And, the Research and Statistics Section of the Board's Legislative and Research Division determined that the proposed amendments will have an insignificant or negligible revenue impact. (See Exhibit 1 to Formal Issue Paper 14-006.) Therefore, the Board estimates that the proposed amendments will not have a measurable economic impact on individuals and business. And, the Board has determined that the proposed amendments to Regulation 1591 are not a major regulation, as defined in Government Code section 11342.548 and California Code of Regulations, title 1, section 2000, because the Board has estimated that the proposed amendments will not have an economic impact on California business enterprises and individuals in an amount exceeding fifty million dollars ($50,000,000) during any 12-month period.

Further, based on these facts and all of the information in the rulemaking file, the Board has also determined that the adoption of the proposed amendments to Regulation 1591 will neither create nor eliminate jobs in the State of California nor result in the elimination of existing businesses nor create or expand business in the State of California.

Furthermore, Regulation 1591 does not regulate the health and welfare of California residents, worker safety, or the state's environment. Therefore, the Board has also determined that the adoption of the proposed amendments to Regulation 1591 will not affect the benefits of Regulation 1591 to the health and welfare of California residents, worker safety, or the state's environment.

The forgoing information also provides the factual basis for the Board's initial determination that the adoption of the proposed amendments to Regulation 1591 will not have a significant adverse economic impact on business.

The proposed amendments to Regulation 1591 may affect small businesses.